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The Honorable Robert C. Byrd
Chairman
Committee on Appropriations
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This letter is in response to the General Accounting Office (GAO) report entitled *EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance* (GAO-01-536; June 2001) concerning potential conflict-of-interest and bias issues relating to the Environmental Protection Agency's (EPA) Science Advisory Board (SAB) peer review panels. Let me assure you that the Agency and the members of the SAB take the GAO findings very seriously. As a result, in concert with the leadership of the Board, we are moving forward on a number of fronts to ensure that outcomes of panel reviews reflect the considerations of groups of technically expert, demonstrably independent advisors who are free of conflicts of interest.

As you know, the report presents GAO's findings and recommendations on SAB peer review panels. In short, GAO presented a series of recommendations to EPA that focus on the following: (1) the independence and balance of viewpoints and expertise on the peer review panels; (2) the availability of information to the public on the panelists and on meeting discussions; and (3) the public's opportunity to comment on proposed panel members.

EPA and the SAB agree with GAO's recommendations and are developing and implementing processes to address the issues identified in the report. Specifically, the Agency is partnering with the SAB Executive Committee (EC), through its Policy and Procedures Subcommittee (PPS), to devise and implement these changes.

As a part of its outreach effort, the PPS sent letters to more than a dozen organizations, including industry and environmental groups, requesting comments on the SAB policies and procedures. The letters and comments received have been posted on the SAB web site in order to inform the broader public.

GAO Recommendation A: Develop policies and procedures that better identify and mitigate potential conflicts of interest and support the development of balanced panels.

GAO cites four changes to address the recommendation:

Recommended Change 1

Determine whether each panel will be reviewing a “particular matter” before selecting the panel in order to identify the financial conflict-of-interest requirements, if any, to which the panelists will be subject.

EPA Response

The Office of the Science Advisory Board (OSAB) is taking a number of steps to address this concern:

- (a) The OSAB, in cooperation with the EPA Office of General Counsel, is conducting training sessions for SAB Designated Federal Officers (DFOs) in order to develop and demonstrate skill in making the appropriate distinctions between issues with and without conflict-of-interest;
- (b) DFOs are also determining and documenting whether proposed projects for SAB review concern “particular matters” that may involve conflict-of-interest; and
- (c) The SAB Staff Director is reviewing and approving these determinations in each instance.

Recommended Change 2

Obtain and evaluate relevant background information on peer review panel candidates before appointing panel members. The evaluation should include explicitly discussing with potential panelists (1) items not adequately reported and/or items that were “not asked for” on the confidential financial disclosure form, as well as items reported that could present conflicts of interest; (2) other information relevant to assessing impartiality, such as research conducted and previous public statements or positions on the matter being reviewed, interest of the employer or clients in the matter, participation in legal proceedings, work for affected industries, and sources of prior or current research grants that could be affected by the matter; and (3) whether they have any potential conflicts of interest related to the specific panel being established. Further, pertinent information obtained from discussions between SAB staff and the panelists should be documented.

EPA Response

In cooperation with the PPS, the Agency is taking a series of actions to address these concerns:

- (a) The EPA Office of General Counsel is working with the Office of Government Ethics (OGE) to discuss alternate approaches that would allow the Agency to gather the type of information mentioned in the GAO report;
- (b) At public meetings, each panelist now provides a written “extended background statement” that covers many of these areas, is distributed to the public, and becomes part of the public record;
- (c) Collection and maintenance of the OGE Form 450 (confidential disclosure form) are being centralized by taking the locked cabinet in which they have been stored, placing it in a lockable office, and instituting a custodial role for a specific staff person;
- (d) The OGE Form 450s are now reviewed by SAB Staff prior to each meeting at which a peer review panel member addresses a new topic, in contrast to the once-a-year practice in the past; and
- (e) We are implementing standard procedures to conduct and document discussions (based on questions from EPA’s *Peer Review Handbook*) with potential panel members regarding bias and conflict-of-interest.

Recommended Change 3

Develop training that clearly identifies for the panelists the conflict-of-interest requirements that apply to them, addresses impartiality, and identifies the background information the staff office needs from the panelists to assess (1) the appropriateness of their participation on specific panels and (2) the balance of viewpoints and expertise on the panels themselves.

EPA Response

EPA agrees with this recommended change and will implement it. Specifically, the OSAB will:

- (a) Conduct monthly training exercises for DFOs in handling and assessing conflict-of-interest and bias information;
- (b) Develop, with input from the PPS, a succinct lay-language summary explanation of relevant conflict-of-interest and bias issues. The document is being patterned after related materials produced by the National Research Council;

- (c) Conduct at least annual ethics discussions with panel members at public meetings;
- (d) Deliver ethics training via teleconference and internet for panelists before panel meetings; and
- (e) Update data systems to reflect more accurately the type and frequency of training received by individual panel members.

Recommended Change 4

Develop criteria for and guidance on the process to be used to achieve the proper balance of viewpoints and expertise on peer review panels.

EPA Response

The Agency is working with the PPS to develop and implement these criteria and guidance. The OSAB is already:

- (a) Asking potential panelists to identify any sources of bias;
- (b) Developing methods for analyzing data related to balance and expertise;
- (c) Soliciting input from the public through the posting of biosketches of candidates for panel membership on the SAB web site. Public comments will inform the final selection of panel members; and
- (d) Benchmarking with practices at the National Academy of Sciences and the Food and Drug Administration.

Over the next year, the OSAB, in collaboration with the PPS, will further refine this process.

GAO Recommendation B: GAO further recommends that the EPA Administrator direct the Science Advisory Board to (1) provide consistent, relevant information to the public about panelists in order to enable the public to sufficiently understand the points of view represented on a panel; and (2) ensure that this information is properly recorded in meeting minutes.

EPA Response

EPA agrees with this recommendation. Working with the PPS, the OSAB has already:

- (a) Contacted more than 20 non-governmental organizations to assess the information needs and recommendations regarding the background of panelists and to determine what information EPA may legally share with the public;

- (b) Placed information about panel members on its web site; and
- (c) Expanded the information that is made available to the public at public meetings and documented it in writing for inclusion in the minutes of the meeting.

GAO Recommendation C: GAO recommends that the Board consider allowing the public the opportunity to comment on proposed panels before final selection decisions are made.

EPA Response

EPA agrees with the recommendation. As noted above, we have already initiated the practice of posting names and background information of enlisted panel members on the SAB web site. As the implementation moves forward, this practice will be expanded to include solicitation of public comment on tentative panel members before the final selection decisions are made.

In summary, the Agency and the leadership of the SAB are taking the GAO report quite seriously by working together to develop mutually workable procedures that follow through on the GAO recommendations and inform the public along the way. Also, as a result of lessons learned from implementing what we have described herein, the Agency and the PPS will undoubtedly make further modifications to improve the process further. In all cases, however, the Agency and the Board will carry out their joint commitment to confront directly the concerns that have been raised in our – and the public's – mind as a result of the GAO report.

Sincerely,

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Michael W.S. Ryan
Deputy Chief Financial Officer